

REMARKS

Status of the Claims

Claims 10 and 22-28 are pending. Claim 29 has been canceled and incorporated into claim 10. No new matter has been added.

Claim Rejection under 35 U.S.C. § 103(a)

Claims 10 and 22-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gensthaler (*Pharmazeutische Zeitung*, 2001, 146(7): 35-36) (“Gensthaler”) in view of Leynadier *et al.* (*Acta Otorhinolaryngol Bel*, 2001, 55(4): 305-312) (“Leynadier”), and over Salmun *et al.* (US2003/0236275) (“Salmun”). For the reasons applicants previously made of record and those presented hereinbelow, the applicants respectfully traverse.

Submitted herewith in support of their traversal is the Rule 132 Declaration of Jean Bousquet., M.D., Ph.D. Dr. Bousquet is an independent and recognized expert in the field of allergic rhinitis, having authored or co-authored more than 500 publications in peer-reviewed journals over roughly 30-years, most in the field of allergies and allergic reactions. Dr. Bousquet was the chairmen of the ARIA initiative (Allergic Rhinitis and its Impact on Asthma) published in 2001 (*J Allergy Clin Immunol*) in collaboration with the World Health Organization (WHO),¹ is the current chairman of the WHO Global Alliance against Chronic Respiratory Diseases (GARD), and is the recipient of numerous awards. Dr. Bousquet’s CV and a list of his publications accompany his Declaration.

Dr. Bousquet has reviewed the publications on which the present obviousness rejections are based ((a) Gensthaler in view of Leynadier and b) Salmun) and the Office’s basis for rejection. As explained in his Declaration, Dr. Bousquet’s opinion is that at the priority date of the present application (December 2002) one of ordinary skill in the art could not have and would not have predicted with a reasonable degree of certainty or reasonably expected that patients suffering from persistent allergic rhinitis could be successfully treated with Levocetirizine for a period of more than three months (as presently claimed) based on the teachings of these publications relied upon by the Office.

¹ Updated in 2008 (*Allergy*, 2008), ARIA is the initiative which proposed and validated the concept of intermittent (IAR) and persistent allergic rhinitis (PER). The 2001 publication was translated into 52 languages.

Dr. Bousquet explains that SAR and PAR, which are the subject of the Gensthaler, Leynadier et al., and Salmun, were determined to be inaccurate and inadequate classifications for allergic rhinitis for a number of reasons (Bousquet Declaration paragraph 11). Dr. Bousquet also attests that SAR and PAR cannot be used interchangeably with the new classifications of IAR or PER because they do not describe allergic rhinitis sufferers sharing a single or closely related set of etiologies. As Dr. Bousquet explains, “intermittent” and “persistent” are not synonymous with “seasonal” and “perennial”.

Dr. Bousquet further explains the differences between SAR and PAR on the one hand and PER on the other in paragraph 15 and then goes on to explain in paragraph 16 why the deficiencies of the SAR/PAR designations along with the differences between SAR/PAR and PER would make it impossible at the priority date of the present application for one of ordinary skill in the art to predict that a more than 3-month course of treatment of a patient suffering from PER could have reasonably been predicted or expected to be successful based on the teachings of Gensthaler in view of Leynadier, or Salmun.

Dr. Bousquet also refutes the Office’s assertion that one of ordinary skill in the art would have expected a 3-month treatment of a PER-suffering patient with Levocetirizine to be successful based Gensthaler in view of Leynadier, or Salmun, merely because SAR/PAR share common symptoms with PER. Dr. Bousquet opines that the Office’s reasoning is flawed for the reasons he outlines in his Declaration.

The only rationale for the present rejections seems to be that SAR and PER both relate to allergic rhinitis and, therefore, successful results observed in the treatment of SAR could be reasonably expected in the treatment of PER. Dr. Bousquet’s expert Declaration and scientific-and evidence-based reasoning establish that this rationale is incorrect.

The applicants respectfully submit that the Office has not presented any scientific evidence in support of its supposition that the results reported in Gensthaler, Leynadier, and Salmun relating to SAR can be extended to PER. All the only evidence of record establishes that one of ordinary skill in the art at the priority date of the present application could not have reasonably predicted or expected that a patient suffering from PER could be successfully treated with Levocetirizine for a period of more than 3-months.

In view of the foregoing, therefore, the applicants respectfully submit that the present claims cannot be obvious over Gensthaler in view of Leynadier or over Salmun and respectfully request withdrawal of the rejections based on 35 U.S.C. § 103(a).

If there are any questions or comments regarding this response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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